DIAGNOSTIC KIT FLEXIBLE ASSEMBLY SYSTEM AND METHOD OF USING THE SAME

FIELD OF THE INVENTION

[01] The present invention is in the field of assembly or manufacturing systems and methods for the production of diagnostic medical test kits.

BACKGROUND OF THE INVENTION

[02] Assembly or manufacturing systems and methods have been devised in the past for producing diagnostic medical test kits (e.g., at-home pregnancy test kit). However, the inventor is not aware of a diagnostic medical test kit assembly system and method that is automatic, high-throughput, in-line, and flexible in nature to allow for families of related diagnostic medical test kits or different products to be assembled with the same system with minimum manual product changeover time.

SUMMARY OF THE INVENTION

[03] Accordingly, an aspect of the invention involves a method of assembling a diagnostic medical test kit. The method includes the following steps:

a) providing an automatic assembly system including an assembly line and a parallel return line, the assembly line and the return line including conveyors running in opposite directions and a start end and a return end, a plurality of pallets carrying the components of the medical test kit during assembly, a plurality of work stations disposed along the assembly line to perform assembly steps on the components of the medical test kit, a start end pallet transfer mechanism disposed at the start end of the

assembly line and the return line to transfer the pallets from the return line to the assembly line, and a finish end pallet transfer mechanism disposed at the finish end of the assembly line and the return line to transfer the pallets from the assembly line to the return line;

b) providing a plurality of empty pallets on the conveyor of the return line;

c) moving the empty pallets on the conveyor of the return line to the start end of the return line;

d) transferring the empty pallets from the start end of the return line to the start end of the assembly line with the start end pallet transfer mechanism;

e) moving the pallets on the conveyor of the assembly line to the plurality of work stations and using the pallets as carriers for a partially completed and completed diagnostic medical test kit;

f) assembling the components of the diagnostic medical test kit at the plurality of work stations;

g) transferring completed diagnostic medical test kits from the pallets, producing empty pallets;

h) transferring faulty diagnostic medical test kits from the pallets, producing empty pallets;

i) moving the empty pallets on the convey of the assembly line to the finish end of the assembly line;

j) transferring the empty pallets from the finish end of the assembly line to the start end of the return line;

k) repeating steps c-j above.

[04] Another aspect of the invention involves an automatic diagnostic medical test kit assembly system including an assembly line having a start end, a return end, a conveyor running in a direction; a return line parallel to the assembly line and having a start end, a return end, and a conveyor running in a direction opposite of that of the conveyor of the assembly line; a plurality of pallets carrying components of the medical test kit during assembly; a plurality of work stations disposed along the assembly line to perform assembly steps on the components of the medical test kit; a start end pallet transfer mechanism disposed at the start end of the assembly line and the return line to transfer the pallets from the return line to the assembly line; and a finish end pallet transfer mechanism disposed at the finish end of the assembly line and the return line to transfer the pallets from the assembly line to the return line.

[05] Further objects and advantages will be apparent to those skilled in the art after a review of the drawings and the detailed description of the preferred embodiments set forth below.

BRIEF DESCRIPTION OF THE DRAWINGS

[06] FIG. 1 is a top plan view of an embodiment of a diagnostic medical test kit assembly system.

[07] FIG. 2 is a front elevational view of the diagnostic medical test kit assembly system of FIG. 1 taken along line 2-2 of FIG. 1.

[08] FIG. 3 is a right side elevational view of the diagnostic medical test kit assembly system of FIG. 1 taken along line 3-3 of FIG. 1.

[09] FIG. 4A is an exploded perspective view of an embodiment of a diagnostic medical test kit assembly.

[10] FIG. 4B is an exploded perspective view of an alternative embodiment of a diagnostic medical test kit assembly.

[11] FIG. 4C is an exploded perspective view of an embodiment of a diagnostic medical test card assembly.

[12] FIG. 5 is a bottom perspective view of an embodiment of a pallet for carrying the diagnostic medical test kit assembly.

[13] FIG. 6 is a top perspective view of the pallet illustrated in FIG. 5.

[14] FIG. 7 is a top perspective view an alternative embodiment of a pallet for carrying a different format diagnostic medical test kit assembly.

[15] FIG. 8 is a partial perspective view of embodiments of the indexing conveyor and the queuing conveyor of the diagnostic medical test kit assembly system.

[16] FIGS. 9A and 9B are an exploded perspective view and a perspective view, respectively, of an embodiment of a pallet transfer mechanism for transferring pallets from a queuing conveyor to an indexing conveyor of the diagnostic medical test kit assembly system.

[17] FIG. 10 is a perspective view of an embodiment of a pallet transfer mechanism for transferring pallets from an indexing conveyor to a queuing conveyor of the diagnostic medical test kit assembly system.

[18] FIG. 11 is a perspective view of an embodiment of a base loading station of the diagnostic medical test kit assembly system.

[19] FIG. 12 is a perspective view of an embodiment of a test strip insertion station of the diagnostic medical test kit assembly system.

[20] FIG. 13 is a perspective view of an embodiment of a wick loading station of the diagnostic medical test kit assembly system.

[21] FIG. 14 is a perspective view of an embodiment of a pneumatic press station of the diagnostic medical test kit assembly system.

[22] FIG. 15 is a perspective view of an embodiment of an assembly verification station of the diagnostic medical test kit assembly system.

[23] FIG. 16 is a perspective view of an embodiment of a lifting mechanism of a cap load and assembly station of the diagnostic medical test kit assembly system.

[24] FIG. 17 is a perspective view of an embodiment of a horizontal assembly mechanism of a cap load and assembly station of the diagnostic medical test kit assembly system.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

[25] With reference to FIGS. 1-3, an embodiment of a flexible, adaptable, and expandable assembly system 10 (hereinafter "system") and method of using the same will be described. Although the system 10 and method will be described in conjunction with the assembly of a "stick" type diagnostic medical test kit 18, the system 10 and method are flexible, and, thus, may be easily converted for the assembly of "card" type diagnostic medical test kits or other biodiagnostic devices. The system and method may also be used for the assembly of other devices such as, but not limited to, genomics devices, medical devices, pharmaceutical devices, and cosmetic devices.

[26] The system 10 and method are used to automatically assembly a "stick" type medical test kit (hereinafter "test kit") 18 comprised of an elongated, narrow base 20, one or more test strips 22, a wick 24, a cover 26, and a cap 28. FIG. 4B illustrates an alternative embodiment of a diagnostic medical test kit assembly 30 that the system 10 and method may automatically assemble. The diagnostic medical test kit assembly 30 includes a base 32, one or more test strips 34, a cover 36, and a cap 38. FIG. 4C illustrates an embodiment of a diagnostic medical test card assembly 40 that the system 10 and method may automatically assemble. The diagnostic medical test card assembly 40 includes a base 42, one or more test strips 44, a cover 46, and a tablet 48.

[27] The system 10 is a palletized, intermittent-synchronous, side-by-side system 10 where the work path is linear and the assembly of the test kit 18 is performed on the base 20 (piece that will become eventual product) carried within a pallet 50 (FIGS. 5-7) on an indexing conveyor 140. The pallet 50 functions as a carrier for the base 20 and is indexed along the indexing conveyor 140 to different work stations (140-250), where different assembly steps are performed on the base 20. The pallet 50 includes a bottom 52 (FIG. 5) and a top 54 (FIG. 6). The bottom 52 includes generally rectangular base sections 56 separated by a lateral recess 58. The top 54 includes a carrier plate 60 with a recess or nesting 62 for receiving the base 20 or test kit subassembly during assembly of the test kit 18. FIG. 7 illustrates an alternative embodiment of a pallet 50 for a different test kit format. The assembled test kit 18 is removed from the pallet 50 and delivered to a "good" storage container with other assembled test kits 18. The empty pallet 50 is then delivered to a parallel queuing conveyor 90 running in an opposite direction from that of the indexing conveyor 140. The queuing conveyor 90

delivers the empty pallet 50 to an opposite end of the system 10, where the pallet 50 is transferred to the indexing conveyor 140 to begin the assembly process again. All assembly functions are preferably performed in a "one-up" configuration, one assembly operation per machine cycle. The system 10 preferably runs at least 3,600 cycles per hour with 1 part per cycle, resulting in at least 3,600 parts per hour. After and/or during each component placement operation, a component verification may be automatically performed using a vacuum or a photo-optic sensor, or a vision system.

[28] The system 10 preferably includes multiple system modules 85 that may be added to or removed from the system during product changeover. The queuing conveyor 90 is part of a return line and delivers pallets 50 from a finish end 100 to an opposite start end 110. The queuing conveyor 90 is a linear return accumulating conveyor driven using a variable-speed continuous motion (brushless) DC motor.

[29] With reference to FIGS. 9A and 9B, a start end pallet transfer mechanism or shuttling mechanism 130 is pneumatically driven and transfers the pallets 50 from the start end 110 of the queuing conveyor 90 to the start end 110 of the linear pallet indexing conveyor 140 (hereinafter "indexing conveyor"). The pallet transfer mechanism 130 includes gripper fingers 131, gripper 132, adapter plate 133, vertical transfer mechanism 134, adapter plate 135, horizontal transfer mechanism 136, mounting plate 137, and support assembly 138. Gripper 132 moves the gripper fingers 131 towards and away from each other to grab and release the pallet 50. The gripper 132 moves up and down via vertical transfer mechanism 134. The gripper 132 moves horizontally via horizontal transfer mechanism 136.

[30] With reference to FIG. 10, a finish end pallet transfer mechanism or shuttling mechanism 260 is similar in design to the start end pallet transfer mechanism 130, but transfers the pallets 50 from the finish end 100 of the indexing conveyor 140 to the finish end 100 of the queuing conveyor 90.

[31] With reference to FIGS. 1 and 8, the indexing conveyor 140 is part of an assembly line and is servo-driven and synchronous-intermittent. An upper surface 66 of the indexing conveyor 140 includes a rectangular block-shaped cleat 68 that extends substantially the width of the indexing conveyor 140 and is received by the recess 58 (FIG. 5) on the bottom of the pallet 50. This cleat 68/recess 58 combination allows the pallets 50 to be quickly moved/accelerated on the indexing conveyor 140 without falling off. The indexing conveyor 140 is parallel to the queuing conveyor 90 and shuttles the pallet 50 from start end 110 to the finish end 100. Along the side of the indexing conveyor 140 are a plurality of adjacent, spaced work stations (140-250), each of which perform a different step with respect to the base 20 and will now be described in turn below.

[32] With reference to FIG. 11, a base loading station 150 includes a flexible part feeder 151 used for bulk feeding and singulation of the base 20 and a robot/vision system 152 for picking and placing the bases 20. The flexible part feeder 151 includes an elevated hopper 153, an elevator conveyor 154, a slow, wide, flat conveyor 155, a centering mechanism 156 (with nylon spacing brush), a fast conveyor 157, a return chute 158, and a return conveyor 159. Multiple bases 20 are manually bulk loaded into the elevated hopper 153. After random orientation in the hopper 153, the base 20 is lifted via the elevator conveyor 154 and discharged onto the conveyor 155. The

centering mechanism 156 center the base 20 on the conveyor 155. Bases 20 ride on the conveyor 155 and pass through the nylon brush of the centering mechanism 156. The nylon brush helps to space the bases 20 on the conveyor 155 with respect to each other. The bases 20 drop onto the fast conveyor 157, where they are presented to the robot/vision system 152. A camera of the robot/vision system 152 is used to locate the base 20 on the conveyor 157, and a vacuum head of the robot/vision system 152 is used to capture the base 20. The robot/vision system 152 may move longitudinally with respect to the conveyor 172, may rotate, and the vacuum head may move up and down. The robot/vision system 152 picks and places the base 20 into the recess 62 of the pallet 50. The robot/vision system 152 loads a single base 20 per cycle. Placing the base 20 in the recess 162 of the pallet 50 causes the base 20 to be accurately constrained during subsequent index and assembly operations.

[33] With reference to FIG. 12, one or more test strip insertion stations 160 index, cut, and place a single test strip 22 into the base 20 each assembly cycle. Test strips 22 are singulated from a test strip magazine 161 using a card indexing strip cutter 162. Cutting and placing of strips is accomplished through coordinated motion of a dual axis transfer unit 163 and the card indexing strip cutter 162. A turn assembly 164 includes a top stationary member 165 and a bottom 180-degree rotational member 166. The bottom rotational member 166 includes opposite pick-and-place heads 167, and rotates 180 degrees, back-and-forth. After the card indexing strip cutter 162 cuts a single test strip 22 from the test strip magazine 161, a pick-and-place head 167 captures the cut test strip 22 with vacuum force, rotates 180 degrees, and places the test strip 22 onto the

base 20 in the pallet 50. As the test strip 22 is placed in the pallet 50, the opposite pick-and-place head 167 picks up a new test strip 22.

[34] With reference to FIG. 13, a wick loading station 170 places the wick 24 in the base 20. The wick loading station 170 includes a flexible part feeder 171 including a wide, flat conveyor belt 172. The wick 24 is discharged onto the wide, flat conveyor belt 172, and a robot/vision system 173, which is similar to the robot/vision system 152 described above, picks and places the wick 24 using vacuum force. The robot/vision system 152 loads a single wick 24 on the base 20 per cycle.

[35] A visual inspection work station 180 utilizes a vision system to inspect the cut test strip 22 in the base 20 for a black (or other color) strip, indicating a "bad" or "rejected" portion of strip material. This black (or other color) strip may be applied to the card stock or magazine of test strips 22 at the time of fabrication. The vision system also inspects the subassembly for missing or misaligned strips and/or wicks 24.

[36] The cover load work station 200 is similar in construction and in use to the base loading station 150, and, therefore will only be briefly described. Elements of the cover load work station 200 are identified with the same reference numbers as those of the base loading station 150. The cover load work station 200 includes a flexible part feeder 151 for bulk feeding and singulation of the cover 26. The covers 26 are manually bulk loaded into the elevated hopper 153, and the flexible part feeder 151 presents the covers 26 to the robot/vision system 152, which captures a cover 26 using vacuum force and the cover 26 is placed on the base 20 in the pallet 50. The robot/vision system 152 loads a single cover 26 per cycle.

[37] With reference to FIG. 14, a pneumatic press station 210 assembles the cover 26 to the base 20 with a "snap" fit. The press station 210 includes a pneumatically driven single action press mechanism 211 to apply a known force to the assembly, mechanically and permanently locking the cover 26 to the base 20. The press mechanism 211 includes a movable lower plate 212 connected to reciprocating posts 213, which reciprocate in linear bushings 214. A compressed rubber pad 215 is located on the underside of the lower plate 212. The linear bushings 214 are carried within stationary upper plate 216. The upper stationary plate 216 is supported by vertical uprights 217 and adapter plates 218. A rectangular column 219 extends from the center of the upper stationary plate 216.

[38] With reference to FIG. 15, an assembly verification work station or height check station 220 may be used to verify the full assembly of the test kit 18. The assembly verification work station 220 may include a pneumatically driven vertical transfer mechanism 221 to lower a linear transducer 222 to verify the height of the test kit 18 to verify the complete assembly of the test kit 18. The vertical transfer mechanism 221 may be connected to a vertical tower 223 via a bracket 224. The vertical tower 223 may be supported by an adapter plate 226.

[39] With reference to FIGS. 1, 13, 16, and 17, a cap load and assembly station 230 includes a cap loading system and a cap assembly system. The cap loading system is similar in use and construction to the wick loading station 170 described above, and, therefore, will not be described in much detail and similar elements to those of the wick loading station 170 will be described with like reference numbers. The robot/vision system 173 receives the cap 28 from the flexible part feeder 171 and delivers the cap

28 to the cap assembly system. With reference to FIGS. 16 and 17, the cap assembly system includes a dedicated single-axis pneumatically driven lifting mechanism 232 and a pneumatically driven single-action horizontal assembly mechanism 233. The lifting mechanism 232 includes a vertical transfer device 234 that picks up the assembled test kit 18 using vacuum force from the pallet 50, elevating it to a position horizontally in-line with the horizontal assembly mechanism 233. The horizontal assembly mechanism includes a horizontal transfer device 235 that shuttles the cap 28 onto the test kit 18, applying a known force to the cap 28 and mechanically locking the cap 28 to the test kit 18.

[40] An eject defective product work station 240 includes a pick-and-place mechanism with a vacuum head to lift the test kit 18 from the pallet 50 and place it on an ejector shoot if it is determined that the test kit 18 is defective. The defective test kits 18 are ejected into a "reject" bulk storage container.

[41] An eject good product work station 250 includes a pick-and-place mechanism with a vacuum head to lift the test kit 18 from the pallet 50 and place it on an ejector shoot if it is determined that the test kit 18 is good condition. The good test kits 18 are ejected into a "good" bulk storage container.

[42] A photo-optic sensor may be used to verify removal of the test kit 18 from the pallet 50 to ensure that a pallet 50 with base 20 is not transferred to the queuing conveyor 90.

[43] The palletized, intermittent-synchronous, side-by-side system 10 will now be described in use. Components are manually bulk loaded into the respective hoppers of the respective stations and/or otherwise provided at the respective stations. The pallet

50 is automatically loaded onto the queuing conveyor 90 at finish end 100 and is shuttled to the opposite start end 110 via the queuing conveyor 120. The pallet transfer mechanism 130 transfers the pallet 50 from the queuing conveyor 90 at the start end 110 to the indexing conveyor 140 at the start end 110. The indexing conveyor 140 shuttles the pallet 50 from the start end 110 to the finish end 100 in a opposite direction than the movement of the queuing conveyor 90. The pallet 50 is first shuttled via the indexing conveyor 140 to the base loading work station 150, where the base 20 is loaded into the recess or nesting 62 on the upper-side 54 of the pallet 50. The pallet 50 with base 20 is then shuttled via the indexing conveyor 140 to the test strip insertion work station 160. At this station, the test strip 22 is cut and placed into the base 20. The pallet 50 with base 20 is then shuttled via the indexing conveyor 140 to the wick loading work station 170, where the wick 24 is placed in the base 20. The pallet 50 with base 20 is then shuttled via the indexing conveyor 140 to the visual inspection work station 180, where the test strip 22 is visually inspected by a vision system. The pallet 50 with base 20 is then shuttled via the indexing conveyor 140 to the cover load work station 200 and then shuttled to the pneumatic press station 210, where the cover 26 is placed on the base 20 in the pallet 50 and then subsequently pneumatically pressed onto the base 20. The pallet 50 is then shuttled to the assembly verification work station 230, where a height check of the final product is performed. The pallet 50 with base 20 is then shuttled via the indexing conveyor 140 to the cap load and assembly station 220, where the cap 28 is placed onto the test kit 18 assembly to form the final product. The pallet 50 with final product is then shuttled via the indexing conveyor 140 to the eject defective product work station 240, where the final product is ejected from

the indexing conveyor 140 into a "reject" bulk storage container if the final product is determined to be defective from the height check. The pallet 50 with final product is then shuttled via the indexing conveyor 140 to the eject good product work station 250, where the final product is ejected from the indexing conveyor 140 into a "good" bulk storage container. The pallet 50 without the final product is then shuttled via the indexing conveyor 140 to the pallet transfer mechanism 260 at the finish end 100, where the pallet 50 is transferred over to the queuing conveyor 90 to start the process over. The pallet transfer mechanism 260 is pneumatically driven and transfers the pallets 50 from the finish end 100 of the indexing conveyor 140 to the finish end 100 of the queuing conveyor 90. Bulk removal of assembled test kits 18 from the "good" bin is performed manually.

[44] All assembly functions are performed in a "one-up" configuration, where one assembly operation occurs per machine cycle. One or more control systems control the conveyors of the system, the shuttle transfer mechanisms, and the work stations. The system 10 may include a user interface 270 for interacting with the one or more control systems.

[45] The system 10 can be used with different pallet 50 configurations for different product formats. Work stations can be easily added to the system 10 or removed from the system 10 with minimal manual changeover time for running different product formats. Further, modules 85 may be easily added or removed to the system 10 depending on the product format. Manual adjustments during product changeover may be made using locking micrometer devices, having readable scales for quick reference. The system 10 may utilize slotted adjustments with a maximum of two set positions.

The above allows families of related products or different products to be assembled with the system 10 and method with minimum manual product changeover time.

[46] It will be readily apparent to those skilled in the art that still further changes and modifications in the actual concepts described herein can readily be made without departing from the spirit and scope of the invention as defined by the following claims.